

## **REMARKS**

Claims 1-20 were pending in the application prior to this amendment. By this amendment, claim 16 has been cancelled without prejudice, while claims 21-35 have been added in order for Applicants to more particularly claim what they regard as their invention. Accordingly, Applicants present claims 1-15 and 17-35 to the Examiner for consideration.

### **I. INTRODUCTION.**

Applicants wish to thank the Examiner for taking the time to discuss issues relating to the patentability above-identified application during the Examiner Interview dated May 23, 2001. As discussed during the Examiner Interview, it is Applicants' belief that the compositions and methods disclosed and claimed in the above-identified application are patentable over the prior art of record because the inventive dental bleaching compositions include<sup>1</sup> potassium nitrate within specific ranges or concentrations<sup>1</sup> that are neither taught nor suggested by the prior art. Dental bleaching compositions that include potassium nitrate within the claimed amounts are believed to have surprising and unexpectedly superior properties compared compositions that include greater amounts of potassium nitrate. In support of the arguments made herein, Applicants include herewith the Declaration Under 37 C.F.R. § 1.131 of Dan E. Fischer, DDS ("Fischer Decl.").

Applicants believe, as evidenced by a comparative study discussed more fully below, that dental bleaching compositions that include potassium nitrate in an amount of about 0.01% to about 2% by weight, more preferably in an amount of about 0.1% to about 1% by weight, and most preferably in an amount of about 0.5% by weight, possess the surprising property of being able to provide enhanced tooth whitening compared to dental bleaching compositions that either include no potassium nitrate or at least 3% potassium nitrate. Moreover, as also evidenced by the comparative study, the claimed compositions are believed to provide far superior desensitization of teeth and soft

tissues compared to dental bleaching compositions that include either 3% potassium nitrate or no potassium nitrate. Both of these surprising and unexpected results are counterintuitive in light of the common practice of including about 3-5% potassium nitrate within desensitizing dental compositions. Fischer Decl., ¶ 9.

## II. COMPARATIVE STUDY.

As discussed at page 26, line 1, through page 29, line 4, of the above-identified application, a comparative study was performed comparing the relative desensitizing and whitening ability of five (5) different dental bleaching compositions. Fischer Decl., ¶ 12. The five compositions that were prepared and comparatively tested (identified as compositions A-E, respectively) included the following amounts of carbamide peroxide and potassium nitrate:

<u>Composition</u>	<u>Carbamide Peroxide</u>	<u>KNO<sub>3</sub></u>
A	10%	0%
B	10%	3%
C	10%	3%
D	15%	3%
E	10.5%	0.5%

Application at page 26, line 1, through page 27, line 15; Fischer Decl., ¶ 12.

The results of the comparative study were summarized in the following table found at page 28, lines 1-17, of the above-identified application, with a description of what is meant by each column of data provided beneath the table:

1	2	3	4	5	6	7	8	9
A	266	37 (13.9)	40 (15)	2 (0.8)	3 (1.1)	14	7	5.4
B	294	51 (17.3)	50 (17)	14 (4.8)	3 (1)	17	6	4.6
C	279	65 (23.3)	45 (16.1)	4 (1.4)	3 (1.1)	17	6	6.7
D	256	61 (23.9)	70 (27.6)	13 (5.1)	2 (0.8)	18	2	7.5
E	216	14 (5.3)	4 (2.1)	0 (0)	0 (0)	7	11	8.6

Column 1 = Composition Tested

Column 2 = Total number of days used by all patients in group

Column 3 = Number of days sensitive to hot or cold (% of total days)

Column 4 = Number of days gums sensitive (% of total days)

Column 5 = Number of days tongue sensitive (% of total days)

Column 6 = Number of days throat sensitive (% of total days)

Column 7 = Number of patients reporting sensitivity to anything

Column 8 = Number of patients reporting no sensitivity to anything

Column 9 = Average number of shade tab changes

Fischer Decl., ¶ 13.

As indicated by the data set forth above, the comparative study also surprisingly and unexpectedly indicated that potassium nitrate, when included in a concentration of 3% by weight within dental bleaching compositions having 10% or 15% by weight carbamide peroxide (compositions B-D), actually caused *increased sensitivity*, on average, to hot or cold, as well as greater tongue sensitivity, compared to composition A, which included 10% carbamide peroxide and *no* potassium nitrate. Fischer Decl., ¶ 14. The comparative study thus demonstrated the surprising and unexpected result that potassium nitrate, when blended with a dental bleaching agent in a dental bleaching composition used to bleach teeth, does not behave as a desensitizing agent at all concentrations, particularly at higher concentrations such as 3%. Fischer Decl., ¶ 15.

Because potassium nitrate was known to be a desensitizing agent, and is customarily included in amounts of about 3-5% within desensitizing dental compositions, one of ordinary skill in the art, when reading U.S. Patent Nos. 5,851,512 and 5,855,870, which teach the inclusion of a dental bleaching agent together with potassium nitrate in a single composition to both bleach and desensitize teeth in a single step, would have expected potassium nitrate to provide desensitizing properties at the standard concentration range of about 3-5%. Fischer Decl., ¶ 16. However, the comparative study, as summarized in the above-identified application, demonstrated the entirely counterintuitive and surprising result of potassium nitrate providing much greater desensitization when used within a dental bleaching composition at a concentration of only 0.5% compared to when it was included in a concentration of 3%. Fischer Decl., ¶ 17.

Even more surprisingly and unexpectedly, the dental bleaching composition that included 0.5% potassium nitrate and 10.5% carbamide peroxide (composition E) also provided significantly better whitening of teeth compared to compositions that included either no potassium nitrate (composition A) or 3% potassium nitrate (compositions B-D), even better than composition B, which included 3% potassium nitrate and a higher concentration of carbamide peroxide (15%). Fischer Decl., ¶ 18. In particular, the composition that included 0.5% potassium nitrate (composition E) resulted, on average, in a total of 8.9 shade tab changes during the duration of the study, whereas the composition that included no potassium nitrate (composition A) resulted, on average, in a total of 5.4 shade tab changes, while the compositions that include 3% potassium nitrate (compositions B-D) resulted, on average, in a total of 4.6, 6.7 and 7.5 shade tab changes, respectively. Fischer Decl., ¶ 19.

In summary, the comparative study demonstrated the superiority of including 0.5% potassium nitrate within a desensitizing dental bleaching composition compared to either including no potassium nitrate or 3% potassium nitrate, in terms of significantly decreased tooth sensitivity and

significantly increased tooth whitening, both of which were surprising and unexpected based upon conventional knowledge at the time of the invention. Fischer Decl., ¶ 20.

### III. PRIOR ART.

One of the references cited in a related application was the Dental Products Report published in November 1998, which included an advertisement by Den-Mat, Inc. for a dental bleaching gel that includes a dental bleaching agent and a desensitizing ingredient under the trade name REMBRANDT XTRA COMFORT. This composition was found to include approximately 5% by weight potassium nitrate, as indicated by an analysis performed on REMBRANDT XTRA COMFORT and, on information and belief, REMBRANDT XTRA COMFORT included approximately 5% by weight potassium nitrate at the time the above-identified application was filed. *See* Fischer Decl., ¶ 21.

In order to determine the actual concentration of potassium nitrate, a commercially available sample of REMBRANDT XTRA COMFORT was obtained and analyzed. A sample of OPALESCENCE PF, sold by Ultradent Products, Inc. and which was known to include 0.5% by weight potassium nitrate, was also analyzed using the same testing method in order to confirm the accuracy of the testing method. Fischer Decl., ¶ 22.

As evidenced by the analysis summarized in Exhibit A to the Fischer Decl.<sup>1</sup>, it was determined that REMBRANDT XTRA COMFORT includes 17% by weight carbamide peroxide and 5.17% by weight potassium nitrate, which is about 2-1/2 times greater than the upper range limit of “about 2% by weight” potassium nitrate recited in the broadest claim of the above-identified application, about 5 times greater than the upper limit of the more preferred range (“about 1% by

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<sup>1</sup> Exhibit A has been redacted to delete confidential information relating to non prior art compositions.

weight”), and about 10 times greater than the most preferred amount of “about 0.5% by weight” potassium nitrate. Fischer Decl., ¶ 23.

Because the Dental Products Report is silent as to the identity and concentration of the desensitizing ingredient, and because REMBRANDT XTRA COMFORT was in fact found to include 5.17% by weight potassium nitrate, Applicants believe that the claims are patentable and nonobvious over the Dental Products Report, either alone or in combination with any other reference. Moreover, Applicants are unaware of any prior art reference that teaches or suggests the inclusion of potassium nitrate within the specific range recited in each of the independent claims of the present application. Similarly, Applicants are unaware of any prior art reference that teaches or suggests anything with regard to the surprising and unexpected result of (i) decreased sensitivity and/or (ii) increased tooth whitening resulting from the inclusion of potassium nitrate within the specific ranges recited in each of the independent claims in the present application. For this reason, and in view of the comparative study discussed herein, it is Applicants’ view that the claims are patentable and nonobvious over the prior art of record.

U.S. Patent No. 5,505,933 to Norfleet et al. and U.S. Patent No. 5,256,402 to Prencipe et al. arguably disclose dentifrices (*i.e.* toothpastes) that include a dental bleaching agent and potassium nitrate. However, neither Norfleet et al. nor Prencipe et al. teaches or suggests the specific range for potassium nitrate recited in each of the independent claims of the present application. Nor do Norfleet et al. or Prencipe et al. provide any teaching or suggestion with respect to the criticality of including potassium nitrate in an amount within the specific range recited in the independent claims of the present application. Finally, it should be noted that the dentifrice compositions disclosed in Norfleet et al. and Prencipe et al. include an abrasive, thus further teaching away from those claims which recite a composition or carrier that is “substantially free of abrasives”.

#### **IV. AMENDMENTS AND NEW CLAIMS.**

Applicants have changed the continuation data at the beginning of the application to delete the claim of priority to U.S. application Serial No. 09/190,709, filed November 12, 1998. Accordingly, the earliest effective filing date of the above-identified application is January 31, 2000.

Independent claim 1 has been amended to (i) incorporate the limitation of originally filed claim 16 and (ii) to delete the functional language associated with the potassium nitrate. Applicants believe that independent claim 1 is patentable over the prior art, which does not teach or suggest the specific range of potassium nitrate recited in claim 1.

Dependent claims 2-15 and 19-20, as amended, have essentially the same or broader scope compared to originally filed claims 2-15 and 19-20. Accordingly, Applicants have in nowise intended to surrender any subject matter that may be covered or contemplated under the Doctrine of Equivalents relative to originally filed claims 2-15 and 19-20.

Independent claim 17 has been broadened somewhat, but is still believed to distinguish over the prior of record in view of the claimed concentration range for potassium nitrate.

Independent claim 18 has been amended to recite the composition of claim 1 as now amended, as well as remove other functional language not necessary to distinguish over the art. Claim 18 has also been amended to recite “contacting the person’s teeth with said dental bleaching composition for a time period of at least about 15 minutes”, which further further distinguishes over Norfleet et al. and Principe et al. It is commonly known that the average person brushes for about 60 seconds or less. Hence, one of ordinary skill in the art would not have understood Norfleet et al. or Principe et al. as teaching or suggesting brushing one’s teeth with the disclosed compositions “for a time period of at least about 15 minutes”. This is particularly true in view of the fact that toothpastes are formulated for daily use, and brushing with an abrasive toothpaste every day for 15

minutes or more would be expected to damage an average person's teeth by removing, abrading or otherwise harming the person's tooth enamel.

New dependent claims 21-26 recite specific functional advantages provided by the potassium nitrate. Support for the advantages recited in claims 21-26 is found in the comparative examples set forth at page 28, lines 1-17 of the present application.

New dependent claim 27 was added to recite a bleaching method that includes the use of a dental tray in order to apply the dental bleaching composition to the person's teeth. Support for the use of a dental tray is found at page 6, lines 1-10 of the above-identified application. The term "dental tray" is broadly defined in the application to include any dental tray known in the art.

New independent claim 28 is similar to original claim 1, but recites the functional attributes of potassium nitrate in the alternative.

New independent claim 29 recites a method that includes the use of a dental bleaching composition that recites the disclosed range for potassium nitrate, together with the use of a dental tray. This combination of limitations is believed to distinguish over the prior art of record.

New dependent claims 30-35 are substantially identical to new claims 21-26, discussed above.

In view of the foregoing, no new matter is being added by the claim amendments and new claims.

## **V. CONCLUSION.**

Applicants believe that the claims are presently in allowable form. In the event that the Examiner finds any remaining impediment to the prompt allowance of this application, which could be clarified by a telephonic interview, or which is susceptible to being overcome by means of an

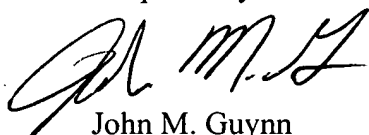


Examiner's Amendment, the Examiner is respectfully requested to initiate the same with the undersigned attorney.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE".

Dated this 25<sup>th</sup> day of June 2001.

Respectfully submitted,



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## **VERSION WITH MARKINGS TO SHOW CHANGES MADE**

### **IN THE SPECIFICATION:**

The paragraph beginning at page 2, line 3, has been amended as follows:

--This application is a continuation-in-part of copending U.S. application Serial No. 09/694,516, filed October 23, 2000, [which is a continuation-in-part of copending U.S. application Serial No. 09/190,709, filed November 12, 1998. This application is also] and a continuation-in-part of copending U.S. application Serial No. 09/494,113, filed January 31, 2000. For purposes of disclosing the present invention, the foregoing applications are incorporated herein by specific reference.--

### **IN THE CLAIMS:**

Claim 16 has been cancelled without prejudice.

Claims 1-15 and 17-20 have been amended as follows:

1. (Amended) A dental bleaching composition for whitening and desensitizing a person's teeth comprising:

at least one dental bleaching agent included in an amount so as to have a tooth whitening effect when contacted with a person's teeth; [.]

potassium nitrate included in an amount of about 0.01% to about 2% by weight of the dental bleaching composition [and so as to enhance the tooth whitening effect of the dental bleaching agent and reduce tooth sensitivity that may be caused by the dental bleaching agent]; and

a carrier into which [the] said dental bleaching agent and potassium nitrate are dispersed,

wherein the dental bleaching composition is substantially free of abrasives.

2. (Amended) A dental bleaching composition as defined in claim 1, wherein [the] said potassium nitrate is included in an amount of about 0.05% to about 1% by weight of the dental bleaching composition.

3. (Amended) A dental bleaching composition as defined in claim 1, wherein [the] said potassium nitrate is included in an amount of about 0.5% by weight of the dental bleaching composition.

4. (Amended) A dental bleaching composition as defined in claim 1, wherein [the] said carrier [includes a] comprises at least one tackifying agent.

5. (Amended) A dental bleaching composition as defined in claim 4, wherein [the] said at least one tackifying agent is [at least one] selected from the group consisting of carboxypolymethylene, [a] gums, [or a] proteins, and mixtures thereof.

6. (Amended) A dental bleaching composition as defined in claim 1, wherein [the] said carrier includes up to about 50% water by weight of the dental bleaching composition.

7. (Amended) A dental bleaching composition as defined in claim 1, wherein [the] said carrier includes at least one polyol.

8. (Amended) A dental bleaching composition as defined in claim 7, wherein [the] said at least one polyol is [at least one] selected from the group consisting of glycerin, propylene glycol, polypropylene glycol, polyethylene glycol, erythritol, sorbitol, [or] mannitol, and mixtures thereof.

9. (Amended) A dental bleaching composition as defined in claim 1, further [including an] comprising at least one antimicrobial agent [which is at least one] selected from the group consisting of chlorhexadine, tetracycline, cetyl pyridinium chloride, benzalkonium chloride, cetyl pyridinium bromide, methyl benzoate, [or] propyl benzoate, and mixtures thereof.

10. (Amended) A dental bleaching composition as defined in claim 1, further [including an] comprising at least one anticariogenic agent [which is at least one] selected from the group consisting of sodium monofluorophosphate, sodium fluoride, [or] stannous fluoride, and mixtures thereof.

11. (Amended) A dental bleaching composition as defined in claim 1, wherein [the] said at least one dental bleaching agent is [at least one] selected from the group consisting of hydrogen peroxide, carbamide peroxide, sodium perborate, benzoyl peroxide, [or] glycerol peroxide, and mixtures thereof.

12. (Amended) A dental bleaching composition as defined in claim 1, wherein [the] said dental bleaching agent is included in an amount of about 0.5% to about 50% by weight of the dental bleaching composition.

13. (Amended) A dental bleaching composition as defined in claim 1, wherein [the] said dental bleaching agent is included in an amount of about 1% to about 30% by weight of the dental bleaching composition.

14. (Amended) A dental bleaching composition as defined in claim 1, wherein [the] said dental bleaching agent is included in an amount of about 3% to about 20% by weight of the dental composition.

15. (Amended) A dental bleaching composition as defined in claim 1, further [including a] comprising at least one bleaching agent stabilizer [that is at least one] selected from the group consisting of EDTA, [a] salts of EDTA, adipic acid, succinic acid, citric acid, [a] nitrates of tin, [or a] phosphates of tin, and mixtures thereof.

17. (Amended) A dental bleaching composition adapted for whitening and desensitizing a person's teeth without brushing or scrubbing, comprising:

at least one dental bleaching agent included in an amount so as to have a tooth whitening effect on a person's teeth without brushing or scrubbing the person's teeth with the dental bleaching composition;

potassium nitrate included in an amount of about 0.01% to about 2% by weight of the dental bleaching composition [and] so as to result in at least one of (i) enhanced [the] tooth whitening [effect of the] by said dental bleaching agent [and] or (ii) reduced [tooth] sensitivity that may be caused by [the] said dental bleaching agent when the dental bleaching [and desensitizing] composition is passively maintained in contact with the person's teeth for a time period of at least about 15 minutes without brushing or scrubbing; and

a carrier that is substantially free of abrasives into which [the] said dental bleaching agent and potassium nitrate are dispersed.

18. (Amended) A method for whitening and desensitizing a person's teeth, the method comprising:

providing a dental bleaching composition including:

a dental bleaching agent included in an amount so as to have a tooth whitening effect when contacted with a person's teeth; [.]

potassium nitrate included in an amount of about 0.01% to about 2% by weight of the dental bleaching composition [and so as to enhance the tooth whitening effect of the dental bleaching agent and reduce tooth sensitivity that may be caused by the dental bleaching agent]; and

a carrier into which [the] said dental bleaching agent and potassium nitrate are dispersed,

wherein the dental bleaching composition is substantially free of abrasives;  
and

contacting the person's teeth with [the] said dental bleaching composition for a time period of at least about 15 minutes [in order that the dental bleaching composition whitens the person's teeth and in order that the potassium nitrate enhances the tooth whitening effect of the dental bleaching agent and reduces tooth sensitivity that may be caused by the dental bleaching agent].

19. (Amended) A method for whitening and desensitizing a person's teeth as defined in claim 18, wherein the person's teeth are contacted with [the] said dental bleaching composition for at least about [15 minutes] 2 hours.

20. (Amended) A method for whitening and desensitizing a person's teeth as defined in claim 18, wherein the person's teeth are contacted with [the] said dental bleaching composition for at least about 1 hour.

New claims 21-35 have been added as follows.

21. (New) A dental bleaching composition as defined in claim 1, wherein said potassium nitrate prevents or reduces sensitivity that may be caused by said dental bleaching agent.

22. (New) A dental bleaching composition as defined in claim 21, wherein said potassium nitrate prevents or reduces sensitivity to hot or cold.

23. (New) A dental bleaching composition as defined in claim 21, wherein said potassium nitrate prevents or reduces gum sensitivity.

24. (New) A dental bleaching composition as defined in claim 21, wherein said potassium nitrate prevents or reduces tongue sensitivity.

25. (New) A dental bleaching composition as defined in claim 21, wherein said potassium nitrate prevents or reduces throat sensitivity.

26. (New) A dental bleaching composition as defined in claim 21, wherein said potassium nitrate causes enhanced whitening of teeth by said dental bleaching agent.

27. (New) A method for whitening and desensitizing a person's teeth as defined in claim 18, further comprising placing said dental bleaching composition into a dental tray and then placing the dental tray over the person's teeth.

28. (New) A dental bleaching composition for whitening and desensitizing a person's teeth comprising:

at least one dental bleaching agent included in an amount so as to have a tooth whitening effect when contacted with a person's teeth;

potassium nitrate included in an amount of about 0.01% to about 2% by weight of the dental bleaching composition so as to result in at least one of (i) an increase in tooth whitening by said dental bleaching agent or (ii) a reduction in sensitivity that may be caused by said dental bleaching agent; and

a carrier into which said dental bleaching agent and potassium nitrate are dispersed.

29. (New) A method for whitening a person's teeth comprising:  
(a) providing a dental bleaching composition comprising:  
(i) a dental bleaching agent included in an amount so as to whiten teeth;  
(ii) potassium nitrate included in an amount of about 0.01% to about 2%  
by weight of the dental bleaching composition; and  
(iii) a carrier into which said dental bleaching agent and potassium nitrate  
are dispersed;  
(b) introducing a quantity of said dental bleaching composition into a dental tray;  
and  
(c) placing the dental tray over the person's teeth for a time period of at least  
about 15 minutes so as to whiten the persons teeth.

30. (New) A method for whitening a person's teeth as defined in claim 29, wherein said  
potassium nitrate prevents or reduces sensitivity that may be caused by said dental bleaching agent.

31. (New) A method for whitening a person's teeth as defined in claim 30, wherein said  
potassium nitrate prevents or reduces sensitivity to hot or cold.

32. (New) A method for whitening a person's teeth as defined in claim 30, wherein said  
potassium nitrate prevents or reduces gum sensitivity.

33. (New) A method for whitening a person's teeth as defined in claim 30, wherein said  
potassium nitrate prevents or reduces tongue sensitivity.

34. (New) A method for whitening a person's teeth as defined in claim 30, wherein said  
potassium nitrate prevents or reduces throat sensitivity.

35. (New) A method for whitening a person's teeth as defined in claim 30, wherein said  
potassium nitrate causes enhanced whitening of teeth by said dental bleaching agent.